

Pesticide Devices & Their Regulatory Requirements

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Pesticides

- FIFRA defines a “pest” broadly to include:
 - Any insect, rodent, nematode, fungus, weed, or
 - Any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other animals).”

Pesticide devices

- FIFRA defines a “device” as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.
- Refer to FIFRA section 2(h).

Pesticide devices (continued)

- Devices can be intended for use on both conventional and antimicrobial pests.
- Antimicrobials Division receives the majority of device determination inquiries.
- Inquiries can be directed to: OPPDdeviceDeterminations@epa.gov, but are often very time-consuming to address.
- Currently, no fee for determinations; under PRIA IV, Device Determinations will be a PRIA action.
- Webpage updates have been drafted to provide the public with answers to frequently asked questions.
 - New workgroup formed: Device Determinations, Barriers, Active Ingredient Determinations

Pesticide devices (continued)

- Webpage updates have been drafted to provide the public with answers to frequently asked questions.
 - New workgroup formed: Device Determinations, Barriers, Active Ingredient Determinations
- Pesticide devices are not required to be registered with EPA but are subject to regulation under FIFRA Section 2(q)(1) (labeling), Section 7 (registration of establishments and production reporting) and Section 8 (books and recordkeeping).
- Pesticide device labeling cannot make false or misleading claims . Each pesticide device product label must include an EPA Establishment Number and is subject to production, labeling, and child-resistant packaging requirements.

Pesticide devices (continued)

- A device must work only by physical means (such as electricity, light or mechanics).
- It **must not** contain (or be sold with) a substance or mixture of substances to perform its intended pesticidal purpose.

Common pesticide devices

- Ultraviolet light systems, ozone generators, water filters and air filters, certain ionizers, and ultrasonic devices for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses;
- Black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects;
- High frequency sound generators, carbide cannons, foils, and rotating devices for which claims are made to repel birds;
- Mole thumpers, sound repellents, foils, and rotating devices for which claims are made to repel mammals; or
- Onsite generators of pesticides (***not sold with any substance***) to be used onsite such as: peracetic acid, hypochlorous acid, or chlorine dioxide (***provided*** resulting pesticide is used onsite and not sold or distributed).

*When what
appears to
be a device
may require
pesticide
registration*

- When the product contains or is sold with a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest this situation may trigger a requirement for pesticide registration.
 - Samsung Washing Machine with silver
 - Insect zapper sold with a substance to attract pests
 - Vacuum cleaner sold with a registered antimicrobial product
- If the device-generated substance is captured and distributed, this situation could require pesticide registration.

Application of a pesticide via a device to provide pest control services

- When a pest control service provider applies a substance that was produced by a device, this action may be considered sale or distribution of an unregistered pesticide e.g., ozone generators used by PCOs or others to mitigate insect infestation or mitigate pathogenic microorganisms
 - antimicrobial solutions generated on-site and applied as part of a service
 - rodent control services that apply a substance in agricultural field and premises

*Application of a
pesticide via a
device to
provide pest
control services-
continued*

- Service providers that might use a substance-producing device to control pests are in varied sectors
 - Commercial cleaning/ janitorial services
 - PCOs
 - Mold remediation and Indoor Air Quality (IAQ) Services
 - Landscape and lawn care service providers

*Recent
attention to
pesticide
devices raises
efficacy
concerns*

- Products on the market are making public health claims that are not consistent with EPA-approved claims made by registered pesticides
 - ultrasonic pest repellers making claims for public health pests based on data rejected by states with device registration programs
 - antimicrobial solutions (e.g., electrolyzed water) generated on-site containing very low concentrations of A.I. but making comparative performance claims for organisms and contact times far beyond those for registered pesticide products

Additional questions related to federal device regulation

- On-site generators are regulated as devices because the resulting substance is not sold or distributed. What are the limitations for transportation and use of generated substances?
- Certain devices make both pesticide and drug claims, e.g., tick removal device that claims freezing inhibits pathogen transmission from tick to human or animal. Is this acceptable?

*Other
Questions?*

Thank you for your attention.